

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

*cr*

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/621,592

07/21/00

JACKOWSKI

G

SKP002

024536

HM12/0717

GENZYME CORPORATION

LEGAL DEPARTMENT

15 PLEASANT ST CONNECTOR

FRAMINGHAM MA 01701-9322

EXAMINER

COOK, L

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

07/17/01

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/621,592

Applicant(s)

JACKOWSKI, GEORGE

Examiner

Lisa V. Cook

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 March 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 21-39 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Amendment Entry***

1. Applicants' response to the Office Action mailed October 3, 2000 (Paper #5 filed 3/30/01) is acknowledged. In response to Amendment-A filed therein claim 22 was canceled while claims 21, 23, 24, 26, 27, and 28 were amended. New claims 34-39 directed to specific methods of assessing patient condition have been added. The amendment directs the invention to different species reading on the general method. In light of the newly submitted claims and further consideration the following Restriction Requirement is imposed: Examiner apologizes for any inconvenience this may cause applicant.

***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- A. Group I - claims 21-34, are drawn to a method for the differential diagnosis of ischemic and hemorrhagic cerebral events, determining brain injury, assessing NSE, endothelial cell membrane protein, MBP, and S100, classified in class 435, subclass 7.92, for example.
  - B. Group II - claims 21-33 and 35, are drawn to a method for the differential diagnosis of ischemic and hemorrhagic cerebral events assessing brain endothelial cell membrane and any other ischemic protein marker, determining patient's for thrombolysis, classified in class 436, subclass 69, for example.

- C. Group III - claims 21-33 and 36, are drawn to a methods for the differential diagnosis of ischemic and hemorrhagic cerebral events assessing S100, increasing concentration of NSE, absent the presence of brain endothelial membrane cell protein , and determining patient's for thrombolysis, classified in class 435, subclass 14, for example.
  - D. Group IV - claims 21-33 and 37, are drawn to a methods for the differential diagnosis of ischemic and hemorrhagic cerebral events assessing S100 and/or increased concentrations of NSE or brain endothelial membrane cell protein thereby determining patient's for thrombolysis, classified in class 435, subclass 7.94, for example.
  - E. Group V - claims 21-33 and 38, are drawn to a methods for the differential diagnosis of ischemic and hemorrhagic cerebral events measuring S100 and MBP to determine severe cerebral edema, classified in class 514, subclass 12, for example.
  - F. Group VI - claims 21-33 and 39, are drawn to a methods for the differential diagnosis of ischemic and hemorrhagic cerebral events measuring NSE and any other protein measuring evolving cerebral infarct, further measuring brain endothelial cell membrane protein to determine patient's for thrombolysis, classified in class 424, subclass 130.1, for example.
3. The inventions are distinct, each from the other because of the following reasons:

Art Unit: 1641

Each of the method Groups I, II, III, IV, V, and VI (A-F) are distinct inventions because they have different modes of operation, different functions, or different effects. With respect to claims 34-39 the variation on the method to assess patient condition, analyzing any number of the patently distinct ischemic markers independently or in any combination thereof (i.e. myelin basic protein[MBP], beta isoform of S100 protein[S100], or neuronal specific enolase[NSE]) and further relating the marker/markers measurement to patently diverse conditions (i.e. detecting brain injuries [TIA/lacunar infarct], susceptibility for thrombolysis, -TIA/lacunar infarct, intracerebral hemorrhage, subarachnoid hemorrhage, cerebral edema) are directed to <sup>divergent</sup> ~~divers~~ and independent species of the recited method that require different procedural steps, different reagents, having different functions and modes of operation.

4. Should applicant traverse on the ground that the species are not patently distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Art Unit: 1641

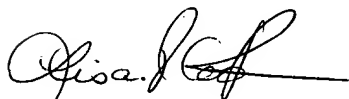
6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Lisa V. Cook  
Art Unit 1641  
CM1-7B17  
07/09/01



CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800-1641